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510(k) Summary of Safety and Effectiveness

ConMed™ ECG Monitoring Electrodes

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for the 510(k) Number _____

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502
Registration Number: 1320894

AUG 0 7 2009

B. Company Contact

Sandy Coveleski
Regulatory Affairs Specialist
ConMed Corporation
525 French Road
Utica, NY 13502

Phone: 315-624-3435
Fax: 315-624-3225
e-mail: sandy_coveleski@mail.conmed.com

C. Device Name

Trade Name:	ConMed™ ECG Monitoring Electrodes
Common Name:	Electrocardiograph Electrode
CLASSIFICATION NAME:	Cardiovascular Devices
Proposed Class/Device:	Class II
Product Code:	DRX
Regulation Number:	21 CFR 870.2360
Panel:	870 Cardiovascular

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D. Predicate Devices

ConMed 2710 CLEARTRACE ^{2} LT Monitoring ECG Electrode
ConMed Corporation
510(k) # K954388

2700 Cleartrace Radiotranslucent Monitoring ECG Electrode
ConMed Andover Medical, Inc
510(k) # K944849

ECG Electrode
ConMed Andover Medical, Inc
510(k) # K944655

1800 Monitoring ECG Electrode And 1870 Diaphoretic Monitoring ECG Electrodes
ConMed Andover Medical, Inc
510(k) # K945836

1700 Monitoring ECG Electrode
ConMed Andover Medical, Inc
510(k) # K946273

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 0 7 2009

ConMed Corporation
c/o Ms. Sandra Coveleski
Regulatory Affairs Specialist
525 French Road
Utica, NY 13502

Re: K091856
Trade/Device Name: ConMed ECG Monitoring Electrode
Regulatory Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (Two)
Product Code: DRX
Dated: July 14, 2009
Received: July 15, 2009

Dear Ms. Coveleski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091856

Indications For Use

510(k) Number (if known) K091856

Device Name: **ConMed™ ECG Monitoring Electrodes**

Indications for use:

The **ConMed™ ECG Monitoring Electrodes** are pre-gelled, single patient use, disposable electrocardiographic electrodes for use as an accessory to ECG equipment for long term or short term monitoring and diagnostic procedures with regular or diaphoretic adhesives.

Prescription Use ___X___ and/or Over-the-counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091856